U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 2, 2021

From: Oluchi Elekwachi, PharmD, MPH, Regulatory Review Officer
OCBQ/DCM/APLB

Through: Lisa Stockbridge, PhD, Branch Chief
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To: Michael Smith, RPM, OVRR\DVRPA\CMC3
Susan Wollersheim, Medical Officer, CBER/OVRR/DVRPA/CRB1

Subject: Review of Proposed Proprietary Name **COMIRNATY** (Pfizer-BioNTech COVID-19) Vaccine
STN: BLA 125742
Applicant: Pfizer, Inc.

Recommendation: **COMIRNATY – Acceptable**

Executive Summary

APLB has completed the proprietary name review (PNR) for the proposed proprietary name, **COMIRNATY**, for Pfizer-BioNTech's COVID-19 vaccine. We recommend that the proposed proprietary name, **COMIRNATY**, be found **Acceptable**.

According to SOPP 8001.4 Review of CBER Regulated Product Proprietary Names, the product office, Office of Vaccine Research and Review (OVRR), makes the final decision on the acceptability of a proposed proprietary name. To meet the PDUFA performance goal, OVRR must communicate this decision to the applicant within 90 days of the receipt of the proprietary name review (PNR) submission. The PDUFA goal date for this PNR is August 17, 2021.

If OVRR accepts our recommendation that the proposed primary proprietary name, **COMIRNATY**, be found **Acceptable**, we offer the following communication-ready language:

> *In consultation with CBER's Advertising and Promotional Labeling Branch, we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations your proposed proprietary name, **COMIRNATY**, is Acceptable.*

OVRR is responsible for communicating CBER's decision to the applicant and should enter the communication issuance date into the FDA electronic record before August 17, 2021, in order to meet the deadline and stop the performance clock. Please notify APLB when this action has been completed.

Background

On May 19, 2021, Pfizer, Inc. submitted a PNR request for its COVID-19 vaccine (BLA 125742). The proposed proprietary name is **COMIRNATY** (pronounced *koh-MER' nah-tee*). The proposed indication is for the active immunization against COVID-19.

According to the sponsor, **COMIRNATY** is an invented word with no inherent meaning. The sponsor did not propose an alternative name.

COMIRNATY will be supplied in 0.45 mL multiple dose vials containing a frozen, concentrated liquid suspension with no preservative. Each vial must be thawed and diluted prior to administration. Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)], then the concentrated liquid in the vial will require dilution with sterile 0.9% Sodium Chloride Injection, USP. After dilution, 0.3 mL doses of vaccine may be withdrawn from the vial, using commercially available disposable sterile syringes with appropriate graduations. Each vial contains sufficient volume to provide 6 individual doses, where each 0.3 mL dose contains 30 µg vaccine for intramuscular injection.

COMIRNATY will be administered intramuscularly as a series of two 30 µg doses (0.3 mL each) according to the following schedule: A single 0.3 mL dose followed by a second 0.3 mL dose 21 days later.

Cartons of **COMIRNATY** multiple dose vials will be shipped in thermal containers over dry ice. Once received, cartons should be removed immediately from the thermal container and stored in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF) until the expiry date printed on the label. Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks.

Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80ºC to -60ºC (-112ºF to -76ºF). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed two weeks.

If an ultra-low temperature freezer is not available, the thermal shipping may be used as temporary storage when consistently re-filled to the top of the container with dry ice. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.

The vaccine will be administered by a qualified healthcare professional.

Method

APLB utilized the FDA Phonetic and Orthographic Computer Analysis (POCA) and the following databases:

1. CBER list of Licensed Products ending June 24, 2021, at http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM149970.pdf
2. DailyMed at http://dailymed.nlm.nih.gov/dailymed/about.cfm
3. Drugs@FDA current through June 24, 2021, at http://www.accessdata.fda.gov/scripts/cder/drugsatfda
4. Electronic Orange Book current through June 24, 2021, at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm
5. Google Internet search at http://www.google.com
6. Micromedex at http://www.micromedexsolutions.com/micromedex2/librarian
7. United States Patent and Trademark Office (USPTO) at http://www.uspto.gov/trademarks/index.jsp
8. USAN Stem at http://www.ama-assn.org/ama1/pub/upload/mm/365/stem-list-cumulative.pdf

APLB also consulted the review team on the proprietary name.

Results

1. Prescreening for Objectionable Naming Practices

The proposed proprietary name, **COMIRNATY**, was screened against the following:

- Obvious similarities in spelling and pronunciation
- Manufacturing characteristics
- Medical and/or coined abbreviations
- Inert or inactive ingredients
- Combination of active ingredients
- United States Adopted Name (USAN) stems
- Same proprietary name for products containing different active ingredients
- Reuse of proprietary names
- Dosage form or route of administration
- Dosing interval
- Established or proper name
- Modifiers as components of a proprietary name
    - Use of numerals as modifiers
    - Device-related modifiers
    - Descriptive modifiers
- Brand name extensions (Umbrella branding)

- Dual proprietary names
- Foreign drug proprietary name
- Prescription-to-OTC switch
- Use of symbols
- Incorporation of the applicant's name

2. Evaluating for Promotional and Safety Concerns

a. Promotional Review [21 CFR 201.10 (c)(3), 202.1 (e)(5)(i), and (e)(6)(i)]

The proposed proprietary name, **COMIRNATY**, is not regarded to be false, misleading, or fanciful.

b. Look-alike Sound-alike Safety Review [21 CFR 201.10 (c)(5)]

Since drug products are prescribed through written, verbal, and/or electronic orders, such forms of communication may lead to medication errors, particularly if proprietary or established names sound or look alike. APLB conducted a search using POCA, with DPRF, Drugs@FDA, Cerner US Legend and OTC, CBER Biologic, Orange Book, and RxNorm as data sources, to identify existing names of concern with potential combined orthographic and phonetic similarity to **COMIRNATY**. There were 105 names found to be moderately phonetically or orthographically similar to **COMIRNATY**. Differences in dose, form, or strength can mitigate confusion with moderately similar names, and none of the names shared dose, form, or strength with **COMIRNATY**.

Recommendation

Given that the moderately similar names had differences in dosage form, dose, and/or strength to **COMIRNATY**, APLB recommends that **COMIRNATY** be found Acceptable at this time.

If you have any questions regarding this review please contact Oluchi Elekwachi, PharmD, MPH Regulatory Review Officer, at 240-402-8930.

BLA 125742

Firm name: Pfizer Ireland Pharmaceuticals

STN: BLA 125742

Letter type: PNR Memorandum

Bcc: OElekwachi
LStockbridge
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DCM Files

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Concurrence box:

MailCode or Office	Name	Approval
APLB	OElekwachi	Oluchi Elekwachi -S3 Digitally signed by Oluchi Elekwachi -S3 DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300216724, cn=Oluchi Elekwachi -S3 Date: 2021.07.02 15:21:33 -04'00'
APLB	LStockbridge	Lisa L. Stockbridge -S Digitally signed by Lisa L. Stockbridge -S Date: 2021.07.02 15:18:18 -04'00'
DCM	RSausville	Robert A. Sausville -S Digitally signed by Robert A. Sausville -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300045570, cn=Robert A. Sausville -S Date: 2021.07.02 16:01:44 -04'00'